

REMARKS

Claims 2-4, 10, 12, 18-20, and 25 are pending. Claims 1, 5-9, 11, 13-17, 21-24 and 26 were previously canceled.

Rejection under 35 USC §102

Claims 2, 3, 18, 19, and 25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wolff et al. (WO 91/12779).

Claim 3 recites a coating including a first layer having (i) a component for reducing or preventing the formation of thrombi; and (ii) a polymer, wherein the component for reducing or preventing the formation of thrombi is blended in the polymer; and a second layer having a component for reducing or preventing infiltration of macrophages in the thrombi, wherein the second layer of the coating is positioned beneath the first layer.

The coating as defined by claim 3 provides an initial release of the component for reducing or preventing the formation of thrombi prior to an initial release of the component for reducing or preventing the infiltration of macrophages in the thrombi.

Claim 18 defines a stent having a coating including a first region having a substance for the treatment of thrombus formation and a second region having anti-inflammatory substance disposed beneath the first region. **The coating provides an initial release of the substance for the treatment of thrombus formation prior to an initial release of the anti-inflammatory substance.**

Claim 19 defines a stent having a coating having a second layer including a substance deposited over a first layer including an anti-inflammatory drug. **The coating provides an initial release of the substance prior to an initial release of the anti-inflammatory drug.**

Claim 25 defines a method that includes implanting a device in a vessel. The device has a coating including a first layer having a component for reducing or preventing the formation of thrombi deposited over a second layer having a component for reducing or preventing the infiltration of macrophages in the thrombi. **The coating provides an initial release of the component for reducing or preventing the formation of thrombi prior to an initial release of the component for reducing or preventing the infiltration of macrophages in the thrombi.**

In contrast, Wolff describes a stent that can include a coating having a polymer and a drug that can be an anticoagulant and/or antiplatelet (aspirin), e.g., the outermost surface of the device in order to elute off very quickly for the first several weeks (Page 10, line 1-2). Wolff does not describe having the two drugs in separate layers in the coating. Therefore, the coating as described in Wolff is incapable of providing a release profile as defined by claim 3, 18, 19 or 25.

Accordingly, Claim 3, 18, and 19 are patentably allowable over Wolff under 35 U.S.C. 102(b). Claim 2 depends on Claim 3 and is therefore patentably allowable over Wolff under 35 U.S.C. §102(b) for at least the same reason.

Rejection under 35 USC § 103

Claim 10 is rejected under 35 U.S.C. 103(a) as being obvious over Wolff in view of U.S. Patent No. 5,464,650 to Berg et al. (“Berg”).

Claim 10 defines a stent for inhibiting restenosis of a mammalian blood vessel. The stent includes a coating having a first layer comprising an anti-thrombogenic substance and a second layer comprising an anti-inflammatory substance positioned beneath the first layer. **The coating provides an initial release of the anti-thrombogenic substance prior to an initial release of the anti-inflammatory substance.** As discussed in the specification of the instant application, a particular release profile of the anti-thrombogenic substance and the anti-inflammatory substance addresses a particular pharmacological or physiological condition of a mammal receiving a coating providing such a release profile. Therefore, the release profile as defined by claim 10 is an important feature of the stent defined by claim 10. As discussed above, Wolff fails to describe or teach such a release profile.

Berg describes a method of coating a stent that can include a drug and a polymer. Berg does not describe or teach a coating that includes two or more drugs. Nor does Berg describe or teach a coating capable of providing a release profile as defined by claim 10. Therefore, Berg does not cure the deficiencies of Wolff. Accordingly, claim 10 is patentably allowable over Wolff in view of Berg under 35 U.S.C. §103(a).

Claim 4 and 12 are rejected under 35 USC 103(a) as being obvious over Wolff in view of U.S. Patent No. 5,756,533 to Iguchi (“Iguchi”).

Claim 4 depends from claim 3, which **requires a coating that provides an initial release of a component for reducing or preventing the formation of thrombi prior to an initial release of a component for reducing or preventing the infiltration of macrophages in the thrombi.** Wolff fails to provide or teach this important feature.

Iguchi describes a medical material that can include an antiplatelet agent and a polymer. Iguchi does not describe or teach a release profile of a drug or agent similar to the one defined by claim 3. Therefore, Iguchi does not cure this deficiency of Wolff. Claim 4 is therefore patentably allowable over Wolff in view of Iguchi under 35 U.S.C. §103(a).

Similarly, claim 12 depends from claim 10, which requires **a coating that provides an initial release of an anti-thrombogenic substance prior to an initial release of an anti-inflammatory substance.** As discussed above, Wolff fails to provide or teach this important feature, and Iguchi does not make up this deficiency of Wolff. Claim 12 is therefore patentably allowable over Wolff in view of Iguchi under 35 U.S.C. §103(a).

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

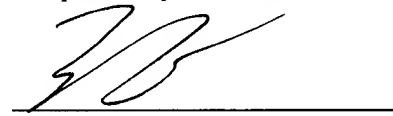
CONCLUSION

Withdrawal of the rejection and allowance of the claims are respectfully requested.

If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

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Respectfully submitted,

A handwritten signature in black ink, appearing to be 'ZB' or similar, written over a horizontal line.

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